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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8.2

Office Action Summary

Application No.

09/939,962

Applicant(s)

FOSTER, MICHAEL B.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/5/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed March 30, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 1-8 and 16-28 has been acknowledged.
3. The new title has been accepted.
4. Claims 9-15, insulin-like growth factor 1, are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. NEW MATTER REJECTION.
7. This rejection is necessitated by Applicants amendments.
8. Specific to claim 9, lines 7-8, the newly added limitation of "by a health professional" has been considered to be new matter because the pointed to support in the original claim 11 does not provide written description basis support to said limitation. It is noted that claim 11

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recites "health professional at a location on-site of said patient administering said dose of hGH" which does not provide written description basis support for the broad limitation of "administered to said patient by a health professional." The newly added limitation could reasonably construed as a health professional being either on-site or remote from the patient, and the administration is achieved either on-site or remotely. Claims 10-12 are rejected for being dependent from claim 9.

CLAIM REJECTIONS - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 9-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burns et al. (US 5,284,133 A).

11. This rejection is maintained with respect to claims 9-15, as recited in the previous office action mailed January 09, 2004.

12. This rejection is necessitated by Applicants amendments.

RESPONSE TO ARGUMENT

13. Applicant argues that Burns et al. does not disclose the limitations of monitoring a patient receiving human growth hormone (hGH) as an anti-aging therapy, hGH is administered by a health professional, monitoring patient responsiveness to the dose, and evaluation by a specialist to determine patient "candidacy". Applicant's arguments have been fully considered and found to be unpersuasive as discussed below. It is noted that the limitations

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of the instant claims have been construed as broadly as reasonable. Therefore, the cited disclosures of Burns et al. are consistent with the limitations of claims 9-15 for anticipating the instant claimed invention.

14. Specific to the argument of monitoring a patient receiving human growth hormone (hGH) as an anti-aging therapy, Applicant discloses that it “is known that administration of human growth hormone...can reduce,..., the above-mentioned effects of aging.” Further, because the Office does not have the facilities for examining and comparing the applicant’s product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

15. Specific to the argument of hGH is administered by a health professional, and evaluation by a specialist to determine patient “candidacy”, Burns et al. discloses a physician can analyze the patient’s treatment history and counsel said patient or adjusting the treatment regiment accordingly (candidacy) (column 11, line 65 to column 12, line 2). Patient returns to the hospital or physician’s office to receive the medication (column 1, lines 34-40). The disclosure of Burns et al. is consistent with the broad limitations of “administered” and “candidacy” of the instant claims.

16. Specific to the argument of monitoring patient responsiveness to the dose, Burns et al. discloses that drug side effects (patient responsiveness to administered drug) can be mitigated

by properly controlling said dosage (column 1, line 66 to column 2, line 1). It is noted that drug side effects is a form of patient responsiveness to treatment.

REJECTION RE-ITERATED

17. Burns et al. discloses a method and system for monitoring the administered dosage of human growth hormone and insulin-like growth factor in a treatment regiment directed to a patient (Abstract etc. and column 6, lines 9 and 24) as in instant claim 14.

18. A physician, pharmacist, or other authorized health care professional at an off-site location analyzes the treatment regiment history (Abstract etc.). During the patient's check-up with the physician (on-site), said physician can analyze the patient's treatment history and counsel said patient or adjusting the treatment regiment accordingly (column 11, line 65 to column 12, line 2). Patient returns to the hospital or physician's office to receive the medication (column 1, lines 34-40), as in instant claims 10-12.

19. Further, Burns et al. discloses that drug side effects (patient responsiveness to administered drug) can be mitigated by properly controlling said dosage (column 1, line 66 to column 2, line 1), as in instant claim 9.

20. The system of Burns et al. comprises a controller which communicates with a recording device and a signal device for alerting patients (Figure 2 and column 10, lines 20-32). A physician could program a computer chip with data directed to dosage and schedule (column 4, lines 51-60), as in instant claims 13 and 15.

CONCLUSION

21. NO CLAIM IS ALLOWED.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

25. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic

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The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

26. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
6/22/04

Armin H. Marschel 6/23/04
ARMIN H. MARSCHEL
TELEPHONIC EXAMINER